

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

**FORM 8-K**

**CURRENT REPORT**

**Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

**Date of Report (Date of earliest event reported): August 10, 2022**

**Spruce Biosciences, Inc.**

(Exact name of Registrant as Specified in Its Charter)

**Delaware**  
(State or Other Jurisdiction  
of Incorporation)

**001-39594**  
(Commission File Number)

**81-2154263**  
(IRS Employer  
Identification No.)

**2001 Junipero Serra Boulevard, Suite 640**  
**Daly City, California**  
(Address of Principal Executive Offices)

**94014**  
(Zip Code)

**Registrant's Telephone Number, Including Area Code: 415-655-4168**

**Not Applicable**

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

**Securities registered pursuant to Section 12(b) of the Act:**

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.0001 per share	SPRB	Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

**Item 2.02 Results of Operations and Financial Condition.**

On August 10, 2022, Spruce Biosciences, Inc. (the “Company”) issued a press release announcing its financial results for the second quarter ended June 30, 2022 and providing corporate updates. The full text of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

All of the information furnished in this Item 2.02 and Item 9.01 (including Exhibit 99.1) shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (“Exchange Act”), and shall not be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

<b>Exhibit Number</b>	<b>Description</b>
99.1	<a href="#">Press Release of Spruce Biosciences, Inc., dated August 10, 2022</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)



## Spruce Biosciences Reports Second Quarter 2022 Financial Results and Provides Corporate Update

*Abstract Accepted for Oral Presentation at International Congress of Endocrinology (ICE 2022)*

*Appointment of P.J. Ramtin as Senior Vice President of Business Operations*

*Expansion of Tildacerfont Patent Portfolio Estate with Key Method of Use Patents*

**San Francisco, Calif. – August 10, 2022 – Spruce Biosciences, Inc.** (Nasdaq: SPRB), a late-stage biopharmaceutical company focused on developing and commercializing novel therapies for rare endocrine disorders with significant unmet medical need, today reported financial results for the second quarter ended June 30, 2022, and provided corporate updates.

“Throughout the second quarter of 2022, we continued to remain focused on clinical study execution. We were pleased to have recently surpassed 25% enrollment in our CAHmelia-203 study and are approaching 25% enrollment in our CAHmelia-204 study,” said Javier Szwarcberg, M.D., M.P.H., Chief Executive Officer of Spruce Biosciences. “I am also pleased to welcome P.J. Ramtin as our Senior Vice President of Business Operations as we continue to expand our development and operational capabilities. With her extensive background in implementing business solutions and bridging real-world insights across all phases of clinical development, we believe that P.J.’s expertise will enrich our ongoing clinical programs for patients and study investigators.”

### Recent Corporate Updates

- **Abstract Accepted for Oral Presentation at ICE 2022:** A submitted abstract was accepted for oral presentation at the International Society of Endocrinology’s ICE 2022 taking place virtually August 25 – 28, 2022. ICE 2022 will be held jointly with the 18th Asia Oceania Congress of Endocrinology (AOCE) and the 21st ASEAN Federation of Endocrine Societies Congress (AFES). The presentation will highlight data from the company’s Phase 2a clinical trials in adults with classic congenital adrenal hyperplasia (CAH) demonstrating an association between glucocorticoid dose with BMI and other glucocorticoid-related comorbidities.

Details are as follows:

**Title:** Association between glucocorticoid dose with BMI and glucocorticoid-related comorbidities: Data from tildacerfont Phase 2a trials in classic congenital adrenal hyperplasia

**Paper Number:** 179

**Paper Reference:** OP-3-6

**Session Date & Time:** 1:10 p.m. - 2:40 p.m. SGT on August 27, 2022

**Presenter:** Will Charlton, MD, Chief Medical Officer of Spruce Biosciences

**Authors:** Mimi Kim, Chris Barnes, and Will Charlton

- **Appointment of P.J. Ramtin as Senior Vice President of Business Operations:** As Senior Vice President of Business Operations, Ms. Ramtin oversees clinical operational excellence and patient engagement. Ms. Ramtin is a seasoned industry executive with over two decades of experience directing and leading commercial and clinical organizations in roles of increasing responsibility across biotech and global pharmaceutical companies. She joins Spruce from BridgeBio, where she served as Vice President, Business Operations. Prior to BridgeBio, Ms. Ramtin held various roles at Regeneron, Genentech, InterMune, AVEO Oncology, and GlaxoSmithKline.
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- **Tildacerfont Patent Portfolio Estate Expanded with Key Method of Use Patents:** Spruce Biosciences continues to expand its patent portfolio for its wholly-owned product candidate tildacerfont to supplement its issued composition of matter patent and market exclusivity afforded by orphan drug designation in the United States and Europe for CAH. In the second quarter, the United States Patent and Trademark Office issued U.S. Patent Number 11,344,557 titled “Corticotropin releasing factor receptor antagonists,” and U.S. Patent Number 11,351,177 titled “Corticotropin releasing factor receptor antagonists.” The newly issued patents cover broad claims regarding the use of a CRF-1 receptor antagonist to reduce 17-hydroxyprogesterone and adrenocorticotrophic hormone (ACTH) concomitantly from baseline in patients with CAH and the use of tildacerfont to reduce ACTH from baseline. These patents expand existing patent exclusivity through 2038.

### Anticipated Upcoming Milestones

- Topline results from the Phase 2 proof of concept clinical trial in polycystic ovary syndrome (PCOS) in the first half of 2023
- Topline safety results from cohort 1 of the Phase 2 pediatric classic CAH clinical trial in the first half of 2023
- Topline results from the CAHmelia-203 clinical trial in adult classic CAH patients with elevated levels of A4 in the second half of 2023
- Topline results from the CAHmelia-204 clinical trial in adult classic CAH patients on supraphysiologic doses of glucocorticoids with normal or near normal levels of A4 in the second half of 2024

### Second Quarter 2022 Financial Results

- **Cash, Cash Equivalents and Investments:** Cash, cash equivalents and investments as of June 30, 2022, were \$99.1 million.
  - **Research and Development (R&D) Expenses:** R&D expenses for the three and six months ended June 30, 2022, were \$9.1 million and \$17.6 million, respectively, compared to \$9.1 million and \$15.8 million, respectively, for the same periods in 2021. The overall increase in R&D expenses was primarily related to progressing clinical development of tildacerfont in adult classic CAH and the initiation of clinical programs in pediatric classic CAH and polycystic ovary syndrome.
  - **General and Administrative (G&A) Expenses:** G&A expenses for the three and six months ended June 30, 2022, were \$2.8 million and \$6.0 million, respectively, compared to \$2.6 million and \$5.7 million, respectively, for the same periods in 2021.
  - **Total Operating Expenses:** Total operating expenses for the three and six months ended June 30, 2022, were \$11.9 million and \$23.6 million, respectively, compared to \$11.7 million and \$21.5 million, respectively, for the same periods in 2021. Stock-based compensation expense for the three and six months ended June 30, 2022, was \$0.9 million and \$2.0 million, respectively, compared to \$1.0 million and \$2.1 million, respectively, for the same periods in 2021. When excluding depreciation and stock-based compensation expenses, total non-GAAP operating expenses for the three and six months ended June 30, 2022, were \$11.0 million and \$21.6 million, respectively, compared to \$10.7 million
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and \$19.4 million for the same periods in 2021.

- **Net Loss:** Net loss for the three and six months ended June 30, 2022, was \$11.9 million compared to \$23.6 million, respectively, compared to \$11.8 million and \$21.7 million, respectively, for the same periods in 2021.

## About Spruce Biosciences

Spruce Biosciences is a late-stage biopharmaceutical company focused on developing and commercializing novel therapies for rare endocrine disorders with significant unmet medical need. Spruce is initially developing its wholly-owned product candidate, tildacerfont, as the potential first non-steroidal therapy for patients suffering from classic congenital adrenal hyperplasia (CAH). Classic CAH is a serious and life-threatening disease with no known novel therapies approved in approximately 50 years. Spruce is also developing tildacerfont for women suffering from polycystic ovary syndrome (PCOS) with primary adrenal androgen excess. To learn more, visit [www.sprucebiosciences.com](http://www.sprucebiosciences.com) and follow us on Twitter @[Spruce Bio](#), [LinkedIn](#), [Facebook](#) and [YouTube](#).

## Forward-Looking Statements

Statements contained in this press release regarding matters that are not historical facts are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements include statements regarding, among other things, the enrollment, results, conduct, progress and timing of Spruce’s clinical trials; the receipt and presentation of topline data from the same; research and development plans; and Spruce’s planned operations. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Words such as “anticipate”, “will”, “believe”, “potential” and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon Spruce’s current expectations and involve assumptions that may never materialize or may prove to be incorrect. Actual results could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, which include, without limitation, risks and uncertainties associated with Spruce’s business in general, the impact of the COVID-19 pandemic and other geopolitical and macroeconomic events, and the other risks described in Spruce’s filings with the U.S. Securities and Exchange Commission. All forward-looking statements contained in this press release speak only as of the date on which they were made and are based on management’s assumptions and estimates as of such date. Spruce undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made, except as required by law.

## Use of Non-GAAP Financial Measures

This release and the reconciliation tables included herein include non-GAAP total operating expenses, which excludes depreciation and stock-based compensation. Spruce excludes depreciation and stock-based compensation because management believes the exclusion of these items is helpful to investors to evaluate Spruce’s recurring operational performance. Spruce management uses this non-GAAP financial measure to monitor and evaluate its operating results and trends on an on-going basis, and internally for operating, budgeting and financial planning purposes. This non-GAAP financial measure should be considered in addition to results prepared in accordance with GAAP but should not be considered a substitute for or superior to GAAP results.

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**SPRUCE BIOSCIENCES, INC.**  
**CONDENSED BALANCE SHEETS**  
**(unaudited)**  
**(in thousands, except share and per share amounts)**

	June 30, 2022	December 31, 2021
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 47,210	\$ 42,748
Short-term investments	46,085	46,221
Prepaid expenses	2,821	2,530
Other current assets	390	396
Total current assets	96,506	91,895
Restricted cash	216	216
Right-of-use assets, net	1,314	1,479
Long-term investments	5,805	32,459
Other assets	674	437
Total assets	\$ 104,515	\$ 126,486
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 1,445	\$ 2,823
Term loan, current portion	811	—
Accrued expenses and other current liabilities	6,953	4,613
Accrued compensation and benefits	893	1,435
Total current liabilities	10,102	8,871
Term loan, net of current portion	4,077	4,878
Lease liability, net of current portion	1,098	1,293
Other liabilities	117	73
Total liabilities	15,394	15,115
Stockholders' equity:		
Preferred stock, \$0.0001 par value, 10,000,000 shares authorized, no shares issued or outstanding as of June 30, 2022 and December 31, 2021	—	—
Common stock, \$0.0001 par value, 200,000,000 shares authorized, 23,560,250 and 23,491,881 shares issued and outstanding as of June 30, 2022 and December 31, 2021, respectively	3	3
Additional paid-in capital	216,731	214,685
Accumulated other comprehensive loss	(845)	(184)
Accumulated deficit	(126,768)	(103,133)
Total stockholders' equity	89,121	111,371
Total liabilities and stockholders' equity	\$ 104,515	\$ 126,486

**SPRUCE BIOSCIENCES, INC.**  
**CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**  
**(unaudited)**  
**(in thousands, except share and per share amounts)**

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	\$ 9,060	\$ 9,119	\$ 17,568	\$ 15,833
General and administrative	2,822	2,595	6,048	5,698
Total operating expenses	<u>11,882</u>	<u>11,714</u>	<u>23,616</u>	<u>21,531</u>
Loss from operations	(11,882)	(11,714)	(23,616)	(21,531)
Interest expense	(94)	(80)	(181)	(169)
Other income, net	104	20	162	39
Net loss	<u>\$ (11,872)</u>	<u>\$ (11,774)</u>	<u>\$ (23,635)</u>	<u>\$ (21,661)</u>
Unrealized loss on available for sale securities	(152)	(29)	(661)	(29)
Comprehensive loss	<u>\$ (12,024)</u>	<u>\$ (11,803)</u>	<u>\$ (24,296)</u>	<u>\$ (21,690)</u>
Net loss per share, basic and diluted	<u>\$ (0.51)</u>	<u>\$ (0.50)</u>	<u>\$ (1.01)</u>	<u>\$ (0.93)</u>
Weighted-average shares of common stock outstanding, basic and diluted	<u>23,493,613</u>	<u>23,329,756</u>	<u>23,492,960</u>	<u>23,306,708</u>



**SPRUCE BIOSCIENCES, INC.**  
**Reconciliation of Total Operating Expenses to Non-GAAP Total Operating Expenses**  
**(unaudited)**  
**(in thousands)**

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2022</u>	<u>2021</u>	<u>2022</u>	<u>2021</u>
Operating expenses:				
Total operating expenses	\$ 11,882	\$ 11,714	\$ 23,616	\$ 21,531
Adjustments:				
Depreciation	9	5	18	9
Stock-based compensation	905	1,010	2,046	2,130
Non-GAAP total operating expenses	<u>\$ 10,968</u>	<u>\$ 10,699</u>	<u>\$ 21,552</u>	<u>\$ 19,392</u>

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